Claims

1. A method for detecting the presence or absence of a medical condition in a tissue, cell type or organ of an individual, comprising the following steps:
a) retrieving a bodily fluid sample from said individual;
b) determining the amount or presence of free floating DNA that originates from said tissue, cell type or organ in said sample; and
c) determining the presence or absence of a medical condition based on the amount or presence of free floating DNA that originates from said tissue, cell type or organ.

2. A method for detecting the presence or absence of a medical condition in a tissue, cell type or organ of an individual, comprising the following steps:
a) retrieving a bodily fluid sample from said individual;
b) determining the amount of total free floating DNA in said sample;
c) determining the amount of free floating DNA that originates from said tissue, cell type or organ in said sample; and
d) determining the presence or absence of a medical condition based on the total amount of free floating DNA and the fraction of free floating DNA that originates from said tissue, cell type or organ.

3. The method according to claim 1 or 2, characterised in that the sample is conditioned before the amount or presence of free floating DNA is determined.

4. The method according to claim 3, characterised in that the sample is conditioned by means of centrifugation, filtering, heating, cooling, concentration or chemical treatment.

5. The method according to one of the preceding claims, characterised in that the amount or presence of DNA originating from a certain organ or tissue is determined by analysing a DNA methylation pattern that is characteristic for said organ, tissue or cell type.

6. The method according to claim 5, characterised in that said methylation pattern is characteristic for said organ, tissue or cell type and not found in other organs, tissues or cell types involved in

the medical condition of interest.

7. The method according to any of the preceding claims, characterised in that the medical condition is a cell proliferative and/or neoplastic disease.

8. The method according to any of the preceding claims, characterised in that the samples are obtained from bodily fluids like whole blood, blood plasma, blood serum, urine, sputum, ejaculate, semen, tears, sweat, saliva, lymph fluid, bronchial lavage, pleural effusion, peritoneal fluid, meningal fluid, amniotic fluid, glandular fluid, fine needle aspirates, nipple aspirate fluid, spinal fluid, conjunctival fluid, vaginal fluid, duodenal juice, pancreatic juice, bile and cerebrospinal fluid from said individual.

9. The method according to one of the preceding claims, characterised in that the methylation pattern is determined by subjecting the DNA to a chemical or enzymatic treatment that converts all unmethylated cytosines in the DNA into uracil but leaves position 5-methylated cytosines unmodified.

10. A method for detecting the absence or presence of a medical condition in an organ, cell type or tissue, comprising performing the following steps:
    a) retrieving a bodily fluid sample;
    b) determining the amount or presence of free floating DNA that exhibits a tissue-, organ- or cell type-characteristic DNA methylation pattern;
    c) concluding, whether there is an abnormal level of free floating DNA that originates from said tissue, cell type or organ; and
    d) concluding, whether a medical condition associated with said tissue, cell type or organ is absent or present.

11. A method for detecting the absence or presence of a medical condition in a specific organ, cell type or tissue, comprising the following steps:
    a) retrieving a bodily fluid sample;
    b) detecting the amount of total free floating DNA in said sample;
    c) determining the amount of free floating DNA that originates from said specific tissue, cell type or organ by determining free floating DNA that exhibits a tissue-, cell type- or organ-characteristic DNA methylation pattern;
    d) determining the fraction of total free floating DNA that originates from said specific tissue,

cell type or organ;

e) concluding, whether an abnormal level of free floating DNA that originates from said specific tissue, cell type or organ is present; and

f) concluding, whether a medical condition associated with said specific tissue, cell type or organ is absent or present.

12. A method for determining the fraction of free floating DNA in a bodily fluid that originates from an organ, cell type or tissue of interest, comprising the following steps:

a) retrieving a bodily fluid sample;

b) conditioning said sample in order to allow a binding of free floating DNA to a surface;

c) binding an essential fraction of said total free floating DNA to said surface;

d) detecting the amount of total free floating DNA by measuring the amount of DNA bound to said surface;

e) subjecting said surface comprising said bound DNA to a chemical and/or enzymatic treatment that converts all unmethylated cytosines in the DNA into uracil but leaves position-5 methylated cytosines unmodified;

f) amplifying the treated DNA;

g) analysing several methylation-specific positions in said treated DNA, and thereby determining the amount of DNA that exhibits a tissue, cell type or organ-characteristic DNA methylation pattern; and

h) determining the fraction of total free floating DNA that originates from said tissue, cell type or organ.

13. The method of claim 12, comprising the following additional steps:

i) concluding, whether said DNA originates from said tissue, cell type or organ, if there is an abnormal level of total free floating DNA; and

j) concluding, whether a medical condition associated with said tissue, cell type or organ is present.

14. The method of claim 10, comprising the following additional step:

e) concluding, which kind of further diagnostic tests will have to be employed.

15. The method of claim 10, comprising the following additional step:

e) concluding, to which kind of specialist the patient might be referred to.

16. The method according to any of the preceding claims, characterised in that the total amount of free floating DNA is measured by intercalating fluorescent dyes or other dyes changing their fluorescence properties when binding to DNA, hybridisation to DNA specific probes including, but not limited to oligonucleotides or PNA oligomers, real time PCR assays or other real time amplification procedures, UV-Vis absorbance or in general amplification procedures with subsequent determination of the amount of product formed.

17. A method for diagnosing a disease or medical condition, comprising a method according to any of the preceding claims.

18. A kit for determining the total amount of free floating DNA in serum, comprising:
    - a surface to bind DNA floating in a sample volume of bodily fluid,
    - a means for detecting the amount of DNA bound to this solid surface,
    - reagents to chemically or enzymatically modify the DNA bound to the surface,
    - a container to host the surface and said reagents, and
    - a means to control and adjust the temperature in this chamber.

19. Use of the method according to the claims above for guiding a physicians' selection on employing further diagnostic tests.

20. Use of the method according to the claims above for guiding the decision of a general physicist to refer a patient to a specific kind of specialist.